CLAIMS

1. Process of making crystals of 9-((1,3-DIHYDROXYPROPAN-2-YLOXY)METHYL)-2-AMINO-1H-PURIN-6-(9H)-ONE, free from alkaline residues characterized by comprising the following steps:

   a) Suspending the 9-((1,3-DIHYDROXYPROPAN-2-YLOXY)METHYL)-2-AMINO-1H-PURIN-6-(9H)-ONE in demineralized water;

   b) Elevating the pH to a range between 10.5 and 12.5 by adding inorganic bases;

   c) Elevating the temperature of the resulting solution 1(b) to a range between 75° and 90°C;

   d) Adding inorganic or organic acids adjusting the pH in a range from 4.5 to 5.5;

   e) Cooling the solution to a temperature ranging from 5° to 7°C and keeping the resulting crystals of 9-((1,3-DIHYDROXYPROPAN-2-YLOXY)METHYL)-2-AMINO-1H-PURIN-6-(9H)-ONE under stirring for 25 to 40 minutes;

   f) Filtering the resulting crystals from 1(e) and washing with an organic solvent selected from the group comprising acetone, ethanol, methanol and isopropanol;

   g) Intense refluxing the resulting crystals from 1(f) in an organic solvent selected from the group comprising methanol, ethanol, propanol, isopropanol and butanol, for a period of time ranging from 3 to 4 hours;

   h) Cooling the resulting suspension from 1(g) to a temperature ranging from 20° and 30°C, filtering the crystals and drying them under vacuum and under a temperature ranging from 60° and 80°C.

2. Process according to claim 1, characterized by the inorganic base used in 1(b) being selected from the group comprising potassium hydroxide, lithium hydroxide and sodium hydroxide.

3. Process according to claim 2, characterized by the inorganic base is sodium hydroxide.

4. Process according to claim 1, characterized by the organic solvent used in steps 1(f) and 1(g) is isopropanol.

5. A ready-for-use pharmaceutical formulation sterile, stable, in closed system, characterized by comprising an injectable aqueous solution of crystals from active principle 9-((1,3-DIHYDROXYPROPAN-2-YLOXY)METHYL)-2-AMINO-1H-PURIN-6-(9H)-ONE as its free acid form, prepared according to process of claim 1, diluted in glucose 5% solution or sodium chloride 0.9% solution, with pH ranging from 3.0 to 6.9, and being packed in a special packing, which is a flexible bag manufactured with a tri-laminated material composed by three distinct layers, being an external layer of polyester, an intermediate layer of polyethylene and the inner layer of propylene copolymer.

6. Pharmaceutical formulation according to claim 5, characterized by the solution is a sodium chloride 0.9% solution, the pH is within the range of 4.5 to 6.9.

7. Pharmaceutical formulation according to claim 5, characterized by the solution is a glucose 5% solution, the pH is within the range of 3.2 to 6.5.

8. An inert closed system for packing a ready-for-use pharmaceutical formulation injectable solution as described in claim 5, characterized by comprising a flexible bag manufactured by a tri-laminated material co-

extrused, composed by three distinct layers, being an external anti-thermic and clear layer of polyester, an intermediate barrier layer of polyethylene and the inner inert layer of propylene copolymer.

9. Use of the closed system as described in claim 8 for packing glucose 5% or sodium chloride 0.9% aqueous solutions comprising 9-((1,3-DIHYDROXYPROPAN-2-YLOXY)METHYL)-2-AMINO-1H-PURIN-6-(9H)-ONE crystals free from alkaline residues prepared according to claim 1.